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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,810	07/10/2001	Kevin R. Mc Intosh	640100-416	7470

7590 09/10/2004

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,810	MC INTOSH ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 3,14,15,18,23,25,29 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,16,17,19-22,24,26-28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments and remarks filed 7/12/04 are acknowledged.
2. Claim 33 stands withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Claims 3, 14, 15, 18, 23, 25, and 29 stand withdrawn from further consideration by the Examiner as being drawn to nonelected species.

Claims 1, 2, 4-13, 16, 17, 19-22, 24, 26-28, and 30-32 are pending and under examination.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2 4, 5, 8, 9, 11-13, 16, 17, 19, 21, 24, 26-28, 30, and 32 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Soiffer et al. (1997), as evidenced by U.S. Patent No. 5,736,396 (1998), for the reasons of record set forth in the action mailed 4/27/04.

Applicant's arguments, filed 3 7/12/04, have been fully considered but they are not persuasive. Applicant argues, "Soiffer, however, does not disclose or even remotely suggest to one of ordinary skill in the art a method of inducing a reduced immune response to donor tissue, or a method of reducing an immune response against recipient tissue by donor tissue, of a method of treating a transplant recipient for graft versus host disease by administering isolated fibroblasts or a supernatant from an isolated fibroblast culture. Therefore, Soiffer does not anticipate Applicants' methods as claimed, nor does Soiffer render Applicants' methods as claimed obvious to one of ordinary skill in the art."

It remains the Examiner's position that the reference teaches the method of the instant claims, i.e., the reference teaches treating as transplant recipient with fibroblasts (given that the transplant itself comprises fibroblasts). The instant application merely further characterizes the result of said

administration, i.e., a reduced immune response. The new limitation of treating with "isolated" fibroblasts is noted. "Isolated", however, can be defined as separated or detached, thus, the fibroblasts need not be purified but only separated from their original source, i.e., the donor's bone. Accordingly, the reference still teaches the method of the instant claims.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6, 7, 10, 20, 22, and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Soiffer et al. in view of Donnelly et al. (1993, IDS), for the reasons of record set forth in the action mailed 4/27/04.

Applicant's arguments, filed 7/12/04, have been fully considered but they are not persuasive. Applicant argues, "Donnelly, however, does not disclose or even remotely suggest to one of ordinary skill in the art that one may administer isolated fibroblasts or a supernatant from an isolated fibroblast culture in order to induce a reduced immune response against donor tissue, to reduce an immune response against recipient tissue by donor tissue, or to treat a transplant recipient for graft versus host disease." "The combination of Soiffer and Donnelly, therefore, does not even remotely suggest to one of ordinary skill in the art that one may administer isolated fibroblasts or a supernatant from an isolated fibroblast culture, in order to induce a reduced immune response against donor tissue, to reduce an immune response against recipient tissue by donor tissue, or to treat a transplant recipient for graft versus host disease."

Note that there is little actual argument in Applicant's remarks, but merely the assertion that the method of the instant claims is not obvious. It remains the Examiner's position that, in view of the combined references, the use of a known immunosuppressive agent (fibroblasts or their supernatant which would contain the soluble immunosuppressive factor) in a method wherein immunosuppression is desirable (tissue transplant) would be obvious.

7. No claim is allowed.


8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
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9/2/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER